

### REMARKS

Claims 1,3 and 7-17 are currently pending in the subject application and are presently under consideration. A version of the claims is found at pages 2-4. Independent claims 1, 10 and 13 have been amended herein. Favorable reconsideration of the subject patent application is respectfully requested in view of the comments and amendments herein.

#### **I. Rejection of Claims 1, 3 and 7-17 Under 35 U.S.C. §103(a)**

Claims 1, 3 and 7-17 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stovall (WO 99/04720) in view of Murphy *et al.* (WO 00/29553). Applicant's representative respectfully requests that this rejection be withdrawn for at least the following reasons. The cited references, either alone or in combination, fail to teach or suggest all aspects set forth in the subject claims.

To reject claims in an application under §103, an examiner must establish a *prima facie* case of obviousness. A *prima facie* case of obviousness is established by a showing of three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second there must be a reasonable expectation of success. ***Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP §706.02(j).*** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not based on the Applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

The claimed invention relates to uses of cultured living connective tissue constructs in surgical repair indications. In particular, amended independent claim 1 recites a method for repairing an intervertebral disc of a patient using a cultured connective tissue construct, comprising: forming at least one opening in the annulus fibrosis of the intervertebral disc; removing at least a portion of the nucleus pulposus through the opening in the annulus fibrosis; ***inserting at least a first cultured connective tissue construct into the opening of the annulus fibrosis; and grafting at least a second cultured connective tissue construct to close the***

*opening in the annulus fibrosis*, wherein the cultured connective tissue constructs comprise: an extracellular matrix layer; and cultured fibroblast cells that synthesize and assemble the layer of extracellular matrix in the absence of exogenous matrix components or synthetic members.

Amended independent claims 10 and 13 recite similar features. Stovall and Murphy *et al.* do not teach or suggest such aspects of the subject claims.

Stovall relates to treating ruptured intervertebral discs by employing polymer solutions, cells or a combination thereof in liquid form. Stovall further allows for the polymer solution, with or without chondrocytes or fibroblasts, to be injected or applied upon or within the annular fibrosis in liquid form. However, the cited reference does not allow for *inserting at least a first cultured connective tissue construct into the opening of the annulus fibrosis; and grafting at least a second cultured connective tissue construct to close the opening in the annulus fibrosis*, as in amended independent claim 1, let alone grafting and/or suturing the second cultured connective tissue construct to tissue surrounding the opening in the annulus fibrosis in order to close the opening, as afforded by amended independent claims 10 and 13.

Murphy *et al.* does not compensate for the aforementioned deficiencies of Stovall. Murphy *et al.* relates to producing cultured tissue constructs. However, Murphy *et al.* is not directed towards the aspects recited in amended independent claims 1, 10 and 13, namely intervertebral disc repair and sealing of a ruptured annular fibrosis.

Moreover, on page 2 of the Office Action, the Examiner asserts that the layer of extracellular matrix as claimed is met by the teachings of Stovall. Applicant's representative respectfully disagrees. Stovall makes not mention of production of an extracellular matrix, let alone an extracellular matrix comprising collagen.

In view of at least the foregoing, it is readily apparent that the cited references, either alone or in combination, do not teach or suggest all aspects of the subject claims. Accordingly, this rejection should be withdrawn.

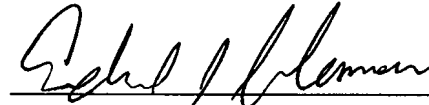
CONCLUSION

The present application is believed to be in condition for allowance in view of the above comments. A prompt action to such end is earnestly solicited.

Should the Examiner believe a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact applicant's undersigned representative at the telephone number below.

Respectfully submitted,

ORGANOGENESIS, INC.

A handwritten signature in cursive script, appearing to read "Edward Adamson", is written over a horizontal line.

Edward Adamson

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